REMARKS

Applicant acknowledges receipt of the Office Action mailed August 2, 2010.

In the Office Action[1], the Examiner rejected claim 39 under 35 U.S.C. § 112, second paragraph; rejected claims 29, 30, 45, 48-55, and 60-65 under 35 U.S.C. § 102(b) as being anticipated by *Lindsay et al.* (U.S. Patent No. 4,433,971); rejected claims 41-44, 58, and 59 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay*; rejected claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg* ("*Buckberg '469*") (U.S. Patent No. 5,011,469); rejected claims 39 and 40 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Strauss et al.* (U.S. Patent No. 5,837,905); rejected claims 46 and 47 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Bringham et al.* (U.S. Patent No. 4,698,207); rejected claims 51 and 63 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg* ("*Buckberg '191*") (U.S. Patent No. 5,643,191); and rejected claims 34-38 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg '469*, and further in view of *Strauss*.

By this Reply, Applicant amends claims 29, 40, and 57-65. Claims 29-65 remain pending. Of these claims, claims 29 and 57-65 are the pending independent claims.

The originally-filed specification, claims, abstract, and drawings fully support amended claims 29, 40, and 57-65. No new matter has been introduced.

Applicant traverses the rejections above and respectfully requests reconsideration for at least the reasons that follow.

[1] The Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicant declines to automatically subscribe to any statement or characterization in the Office Action.

I. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION

Claim 39 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner alleges, "[c]laim 39 recites the limitation 'the second end of the fourth conduit and the first end of the fifth conduit' in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim." (*Office Action*, p. 2, para. 1). Applicant submits that the limitation cited by the Examiner appears in claim 40, not claim 39. Applicant further submits that the rejection of claim 40 under 35 U.S.C. § 112, second paragraph, has been rendered moot by the amendment to claim 40. Applicant therefore requests that the rejection of claim 40 under 35 U.S.C. § 112, second paragraph, be withdrawn.

II. 35 U.S.C. § 102(b) REJECTION

Applicant traverses the rejection of claims 29, 30, 45, 48-55, and 60-65 under 35 U.S.C. § 102(b) as being anticipated by *Lindsay*. Applicant respectfully submits that amended independent claims 29 and 60-65 patentably distinguish over *Lindsay* at least for the reasons described below.

In order to properly establish that *Lindsay* anticipates Applicant's claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue must be found, either expressly described or under principles of inherency, in that single reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *See* M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Amended independent claim 29, and similarly amended independent claims 60-65, recites a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid" (emphases added).

Lindsay discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

Lindsay, however, fails to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added). The Examiner alleges that "Lindsay et al . . . teaches a second chamber 184 having an opening 188 that is closed by a hydrophobic membrane 194." (*Office Action*, p. 3, ll. 3-6). While Applicant does not agree with the Examiner's characterization of *Lindsay* in this fashion, it is indisputable that *Lindsay* fails to disclose every limitation of amended independent claims 29 and 60-65. First, the plastic housing 184, which the Examiner equates to the claimed "second chamber,"

does not have a lid with a vent. *Lindsay* merely discloses a "domed, essentially cylindrical, transparent plastic housing 184 [having] an integral domed top 186 in the center of which is an outlet nipple 188." (*Lindsay*, col. 4, ll. 65-68). In contrast, as described in Applicant's specification, "[t]he disk-shaped upstream portion of the second chamber 14 is defined within a capsule like lid 76 fitting on the upper rim of the cylindrical wall 73 of the second chamber 14." (*Specification*, p. 17, ll. 4-6). Accordingly, *Lindsay* fails to teach or suggest a separate lid, as recited in amended independent claims 29 and 60-65, which fits on a rim of the plastic housing 184.

Second, the hydrophobic filter 194, which the Examiner equates to the claimed "hydrophobic membrane," does not close an opening of a second chamber within a lid. Rather, *Lindsay* merely discloses that "[t]he tube 190 and a hydrophobic filter 194 at the top thereof is part of the disposable system." (*Lindsay*, col. 5, ll. 1-3). Since the hydrophobic filter 194 is attached to a top portion of the tube 190, which is not an integral part of the bubble trap 60, and as discussed above, since *Lindsay* does not disclose that the plastic housing 184 includes a lid, *Lindsay* cannot and does not teach or suggest that the hydrophobic filter 194 closes an opening of a second chamber within a lid. In contrast, as disclosed in Applicant's specification, "the disk-shaped upstream portion of the second chamber 14 is delimited by an inner peripheral wall 77 of the lid 76, which has a frusto-conical inner surface, and by a circular hydrophobic membrane 78 closing an opening of the second chamber 14 within the lid 76 defined by an inner annular shoulder 79." (*Specification*, p. 17, ll. 6-10).

For at least the above reasons, amended independent claims 29 and 60-65 are distinguishable from *Lindsay* and are allowable. Accordingly, claims 30, 45, and 48-55

which depend from claim 29, are allowable at least due to their dependence from allowable independent claim 29, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 29, 30, 45, 48-55, and 60-65 under 35 U.S.C. § 102(b) be withdrawn.

III. 35 U.S.C. § 103(a) REJECTIONS

Applicant traverses the rejection of claims 41-44, 58, and 59 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claims 58 and 59 patentably distinguish over *Lindsay* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. *See* M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. *See* id. "A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention." M.P.E.P. § 2145. Furthermore, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art" at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole

would have been obvious." M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

"[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art." M.P.E.P. § 2141(II). "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." M.P.E.P. § 2141(III).

Amended independent claim 58, and similarly amended independent claim 59, recites, among other things, a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid" (emphases added).

As discussed above, *Lindsay* discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

The Examiner concedes, however, that "Lindsay . . . does not specifically teach the claimed cross-sectional diameter ratios between the first and second chambers of the degassing device (and the resulting flow rates)." (*Office Action*, p. 5, ll. 14-16). *Lindsay* also fails to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), at least for the reasons discussed above. Specifically, the plastic housing 184, which the Examiner equates to the claimed "second chamber," does not have a lid with a vent. Additionally, the hydrophobic filter 194, which the Examiner equates to the claimed "hydrophobic membrane," does not close an opening of a second chamber within a lid.

As explained above, the elements of amended independent claims 58 and 59 are neither taught nor suggested by the cited references. Consequently, in the Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claims. Accordingly, no sufficient reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 58 and 59 and these claims are allowable over the cited reference.

Claims 41-44 are also allowable over *Lindsay* due at least to their dependence from allowable independent claim 29, and due to their additional recitation of novel subject matter. Applicant therefore requests that the rejection of claims 41-44, 58, and 59 under 35 U.S.C. § 103(a) be withdrawn.

Applicant traverses the rejection of claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg '469*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 57 patentably distinguishes over *Lindsay* and *Buckberg '469* at least for the reasons described below.

As discussed above, *Lindsay* discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

The Examiner concedes, however, that "Lindsay . . . is silent on whether the withdrawal line comprises pumps on *both sides* of the oxygenator (such that the withdrawal conduit comprises a fourth conduit extending from the patient access to a pump, and a fifth conduit that extends from said pump to said oxygenator." (*Office Action*, p. 6, ll. 5-8). *Lindsay* also fails to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), at least for the reasons discussed above. Specifically, the plastic housing 184, which the Examiner equates to the claimed "second chamber," does not have a lid with a vent. Additionally, the hydrophobic filter

194, which the Examiner equates to the claimed "hydrophobic membrane," does not close an opening of a second chamber within a lid.

In order to cure the deficiencies of *Lindsay*, the Examiner relies on *Buckberg '469* and contends that "Buckberg . . . teaches an extracorporeal cardioplegia delivery system for oxygenating blood comprising a withdrawal conduit (29, 40), a withdrawal pump 18, an oxygenator 20, a cardioplegia pump 24, and an infusion lumen. The withdrawal pump 18 is configured to apply a negative pressure to the withdrawal conduit, such that blood is sucked through the conduit. Once blood reaches the pump 18, it applies positive pressure to move the blood forward through the oxygenator. Once the blood passes the oxygenator and mixes with other fluids, the cardioplegia pump 24 will reinfuse the fluid into the body." (*Office Action*, p. 6, ll. 10-17).

Buckberg '469, however, merely discloses a method and apparatus for arresting or reversing heart damage from myocardial infarction by using a peripheral, femoral-femoral full bypass along with the venting of the left ventricle wherein the rate at which blood is drawn from the femoral vein and the rate at which the left ventricle is vented are related in a predetermined manner. (*Buckberg '469*, Abstract).

Such teachings, even if present in *Buckberg '469*, which Applicant does not necessarily concede, however, fail to teach or suggest at least a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), as recited in amended independent claim 57.

As explained above, the elements of amended independent claim 57 are neither taught nor suggested by the cited references. Consequently, in the Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 57 and this claim is allowable over the cited references.

Claims 31-33 and 56 are also allowable over *Lindsay* and *Buckberg '469* due at least to their dependence from allowable independent claim 29, and due to their additional recitation of novel subject matter. Applicant therefore requests that the rejection of claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) be withdrawn.

Applicant traverses the rejection of claims 51 and 63 under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg '191*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 63 patentably distinguishes over *Lindsay* and *Buckberg '191* at least for the reasons described below.

As discussed above, *Lindsay* discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means

for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

The Examiner concedes, however, that "Lindsay . . . does not specifically teach that the hydrophobic membrane is disposed adjacent the accumulation of gas bubbles." (*Office Action*, p. 9, ll. 7-9). *Lindsay* also fails to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a deformable hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), at least for the reasons discussed above. Specifically, the plastic housing 184, which the Examiner equates to the claimed "second chamber," does not have a lid with a vent. Additionally, the hydrophobic filter 194, which the Examiner equates to the claimed "hydrophobic membrane," does not close an opening of a second chamber within a lid.

In order to cure the deficiencies of *Lindsay*, the Examiner relies on *Buckberg '191* and contends that "Buckberg . . . teaches a cardioplegia treatment system comprising a degassing chamber for removing gas from blood. Blood passes into a first chamber, then rises into a second chamber. Once in the second chamber, gas bubbles rise to the top portion thereof, where they contact a hydrophobic membrane 68." (*Office Action*, p. 9, ll. 9-13).

Buckberg '191 merely discloses a cardioplegia delivery system which includes a first delivery unit adapted for connection in a manner allowing delivery of cardioplegia fluid to a patient's heart during surgery. A second delivery unit may be added to the cardioplegia delivery system. The second delivery unit includes a heat exchanger for controlling the temperature of the cardioplegia fluid. (*Buckberg '191*, Abstract).

Buckberg '191 further discloses that the air chamber 12 of the cardioplegia delivery system includes a membrane 68 positioned at the top of the air chamber. Membrane 68 is supported by a plurality of support struts 71 which hold the membrane in place and prevent the shape of the membrane from distorting under pressure. (*Buckberg '191*, col. 5, ll. 33-44).

Such teachings, even if present in *Buckberg '191*, which Applicant does not necessarily concede, however, fail to teach or suggest at least a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a deformable hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), as recited in amended independent claim 63. As discussed above, the membrane 68 of *Buckberg '191*, which the Examiner equates to the claimed "hydrophobic membrane," is not deformable because the plurality of support struts 71 hold the membrane 68 in place. In contrast, Applicant's claimed "hydrophobic membrane" does deform under positive pressure because it is only secured at its periphery to the shoulder 79 and it is spaced apart from the lid 76. As disclosed in Applicant's specification referring to an embodiment of the invention, "[t]he hydrophobic membrane 78 is secured (e.g. by gluing) at its periphery to the shoulder 79 . . . The annular shoulder 79 is spaced apart from the top wall 80 of the lid 76 so that the hydrophobic membrane 78 can deform under positive pressure." (*Specification*, p. 17, ll. 10-20).

As explained above, the elements of amended independent claim 63 are neither taught nor suggested by the cited references. Consequently, in the Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor

properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 63 and this claim is allowable over the cited references.

Claim 51 is also allowable over *Lindsay* and *Buckberg '191* due at least to its dependence from allowable independent claim 29, and due to its additional recitation of novel subject matter. Applicant therefore requests that the rejection of claims 51 and 63 under 35 U.S.C. § 103(a) be withdrawn.

Claims 39 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Strauss*; claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Bringham*; and claims 34-38 stand rejected under 35 U.S.C. § 103(a) as being unpatenable over *Lindsay* in view of *Buckberg '469*, and further in view of *Strauss*. Applicant respectfully traverses these rejections and requests that the Examiner withdraw the rejections and allow the claims.

As noted previously, *Lindsay* does not disclose or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), as recited amended independent claim 29. *Strauss*, *Bringham*, and *Buckberg '469* also do not remedy the deficiencies of *Lindsay*.

With respect to *Strauss*, the Examiner asserts that "Strauss et al . . . teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having a plurality of sockets onto which tubing segments are

mounted" (*Office Action*, p. 7, ll. 10-13); with respect to *Bringham*, the Examiner alleges that "Bringham et al . . . teaches an integrated oxygenator and gas removal device wherein blood is inserted tangentially around the inlet to the oxygenator" (*Id.* at p. 8, ll. 14-16); and with respect to *Strauss*, the Examiner asserts that "Strauss teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having pressure-sending cells . . . attached thereto" (*Id.* at p. 10, ll. 8-10). Such teachings, even if present in *Strauss*, *Bringham*, and *Buckberg '469*, which Applicant does not necessarily concede, however, fail to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, [and] a hydrophobic membrane closing an opening of the second chamber within the lid" (emphases added), as recited in allowable amended independent claim 29.

Moreover, claims 34-40, 46, and 47 depend from independent claim 29 and require all elements thereof. As explained above, the elements of independent claim 29 are neither taught nor suggested by the cited references. In addition, in the Office Action, the Examiner has neither properly determined the scope and content of the prior art nor ascertained the differences between the prior art and these claims. No reason has been clearly articulated as to why these claims would have been obvious to one of ordinary skill in view of the prior art and a *prima facie* case of obviousness has not been established for claims 34-40, 46, and 47 at least due to their dependence from allowable amended independent claim 29. Therefore, Applicant requests that the rejection of claims 34-40, 46, and 47 under 35 U.S.C. § 103(a) be withdrawn.

IV. CONCLUSION

Applicant respectfully submits that claims 29-65 are in condition for allowance.

In view of the foregoing, Applicant respectfully requests reconsideration and reexamination of this application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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